

## **REMARKS**

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

### **Amendments to the Specification:**

The specification was amended at page 5, line 29, to insert the inadvertently omitted word "drug" at the end of this paragraph. In addition, the underlined term "ex vivo" was replaced with the italics form to clarify that the previous underlining did not indicate added matter.

Typographical and grammatical errors were corrected at page 12, line 7 (removal of a space before the comma) and at line 10 (replacement of a comma with a period) as well as at page 15, line 22 (insertion of a period at the end of the sentence).

### **Amendments to the Claims:**

Claims 21, 24, 25, and 31-44 are requested to be amended as shown, above.

Claim 21 has been amended to recite "[i]n a method for treating atherosclerosis in a mammalian patient with a statin drug . . ." The addition of the term "atherosclerosis" incorporates the Examiner's suggestion, as found at the top of page 6 of the Office Action as well as in previously presented Claim 22.

Similarly, the deletion of the phrase "lipid profile modifying" and addition of the term "statin" incorporates the Examiner's suggestion, as found in the middle of page 10 of the Office Action. Statins, as a class of lipid profile modifying drugs are disclosed throughout the specification, for example, in the paragraph bridging pages 2 and 3 and in previously presented Claim 23.

Support for the phrase "mammalian patient" can be found throughout the specification, e.g., at page 5, lines 21 and 25.

Finally, the term ex vivo has been changed in this and other claims to be in italics.

Claim 24 has been amended to depend from claim 21, since claim 23, from which claim 24 formerly depended, has been canceled.

Claims 25 and 31-37 have been amended to delete the term "about," as suggested by the Examiner at the bottom of page 6 of the Office Action.

Claim 31 has also been amended to delete the hyphen in the term "ex vivo," to conform to the other claims pending in the application and to place this term in italics.

Claims 32-44 have been amended to delete the phrases "cholesterol modifying" and "cholesterol lowering" and to add the term "statin," as suggested by the Examiner in the middle of page 10 of the Office Action.

Claim 37 have been amended to change the recited daily dosage range for cerivastatin from "about 5 to about 200 mg" to "0.1 to 0.8 mg," as suggested by the Examiner at the bottom of page 4 of the Office action. See, for example, page 15, lines 1-10, of the specification.

No new matter has been added by the above amendments.

Claims 22, 23, and 45-48, are requested to be canceled, without prejudice or disclaimer.

The above amendments have been made, in accordance with the Examiner's suggestions, to place the application in condition for allowance. Applicants are grateful to the Examiner for indicating allowable subject matter and suggesting claim amendments to overcome rejections. Nonetheless, Applicants reserve the right to file and prosecute continuation and/or divisional applications drawn to other aspects of the invention, including subject matter that has been canceled by the above amendments.

While the above amendments presumably obviate the outstanding objections and rejections, each will be separately addressed, below.

#### **Oath/Declaration**

Applicants submit herewith a new Oath/Declaration, which correctly identifies the application and related foreign filings.

**Claim objections**

Claims 23, 25, 32-41, and 45-47 were objected to for the recitation of "cholesterol modifying " and "cholesterol lowering." These phrases no longer appear in the claims.

Claims 25 was objected to for the recitation of "the patient," which allegedly lacked antecedent basis in claim 21. Claim 21 has been amended to provide antecedent basis.

**Rejection under 35 U.S.C. § 112, first paragraph (written description)**

Claim 37 was rejected because the specification allegedly lacked adequate written description for the recited daily dosage of cerivastatin. Claim 37 has been amended to conform to the daily dosage described in the specification.

**Rejection under 35 U.S.C. § 112, first paragraph (enablement)**

Claims 21-41 and 45-48 were rejected as allegedly not being supported by an enabling specification with respect to the full scope of the therapeutic objective. Claim 21, from which other claims identified in the rejection depend, has been amended to recite "atherosclerosis," as suggested by the Examiner, which presumably overcome the rejection. Note that claims 22, 23, and 45-48 have been canceled.

**Rejection under 35 U.S.C. § 112, second paragraph (indefiniteness)**

Claims 25 and 31-37 were rejected for the recitation of "about" with respect to certain ranges. While the term "about" appears to be standard claim language in U.S. patent applications and issued patents, it has nonetheless been deleted from the claims by the above amendments.

**Rejection under 35 U.S.C. § 102(b)**

Claims 21, 22, 38, 42-44, and 48 were rejected over Bisaccia *et al.* (U.S. Pat. No. 5,426,116) in view of the Merck Manual based on the Patent Office's interpretation of the phrases "lipid modifying drug" and "cholesterol-lowering drug." These phrases have been deleted from the claims as suggested by the Examiner at page 10 of the Office Action.

### CONCLUSION

Applicant believes that the present application is now fully in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is encouraged to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 50-0872.

Respectfully submitted,

Date 4/29/05

FOLEY & LARDNER LLP  
Customer Number: 38706  
Telephone: (650) 251-1103  
Facsimile: (650) 856-3710

By Gerald F. Swiss

Gerald F. Swiss  
Attorney for Applicant  
Registration No. 30,113